IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

DIANNE M. DONALDSON and DALE A. DONALDSON,	)	
Plaintiffs,	)	
	)	**Case No. 15-cv-14-SMY**
vs.	)	
JOHNSON & JOHNSON and ETHICON, INC.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

YANDLE, District Judge:

Plaintiffs Dianne M. Donaldson and Dale A. Donaldson filed the instant products liability lawsuit against Defendants Johnson & Johnson and Ethicon, Inc., claiming asserting injuries to Dianne Donaldson from the surgical implantation of two Ethicon pelvic mesh devices. The case was consolidated for pretrial purposes in multi-district litigation ("MDL") proceedings – *In re: Ethicon Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327 – and has been remanded to this Court for trial.

Now before the Court are Defendants' Motion for Summary Judgment (Doc. 31), Defendants' Supplemental Motion for Summary Judgment (Doc. 56), and Defendants' Motion to Strike (Doc. 57). Plaintiffs have responded to motions (Docs. 40, 62, and 63). For the following reasons, Defendants' motions are **GRANTED**.

Procedural Background

Plaintiffs filed this lawsuit in this Court in January 2015 (Doc. 2). The case was transferred to the United States District Court for the Southern District of West Virginia in May 2015 as part

of MDL No. 2327, *In re: Ethicon Inc., Pelvic Repair System Products Liability Litigation*. In the MDL, Plaintiffs filed an Amended Short Form Complaint asserting claims for negligence (Count I), strict liability – manufacturing defect (Count II), strict liability – failure to warn (Count III), strict liability – defective product (Count IV), strict liability – design defect (Count V), fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), negligent misrepresentation (Count IX), negligent infliction of emotional distress (Count X), breach of express warranty (Count XI), breach of implied warranty (Count XII), violation of consumer protection laws (Count XIII), gross negligence (Count XIV), unjust enrichment (Count XV), loss of consortium (Count XVI), punitive damages (Count XVII), and discovery rule and tolling (Count XVIII) (MDL Doc. 13, ¶ 13). Plaintiffs disclosed their experts on June 4, 2018 in accordance with the MDL Court's Wave 8 deadline (Doc. 31-4); they disclosed Donaldson's treating physicians but did not disclose any retained experts. Defendants disclosed their experts on August 13, 2018. Defendants moved for partial summary judgment in the MDL, but the case was remanded to this Court prior to adjudication of Defendants' motion.

Upon remand and after seeking leave, Defendants moved for summary judgment as to all of Plaintiffs' claims. On September 2, 2020, the Court permitted Defendant leave to supplement its summary judgment motion a second time to consider recent discovery conducted by the parties (Doc. 55). Following limited discovery, Defendants again moved for summary judgment.

Factual Background

Construed in the light most favorable to the Plaintiffs, the evidence and reasonable inferences establish the following facts relevant to the pending summary judgment motions: On May 24, 2010, Dr. Michael Schultheis surgically implanted Dianne Donaldson with two transvaginal polypropylene mesh medical devices manufactured by Ethicon, Inc.: a TVT-Secur

and a Prosima (collectively, "the devices") (Doc. 32-1, at 6). Donaldson was 54 years old at the time. *Id*. She had been diagnosed with stress urinary incontinence and anterior pelvic organ prolapse and the surgery was aimed at addressing those issues. *Id.* Several years after the surgery, mesh from the devices eroded into Donaldson's bladder, vagina, and adjacent tissues. *Id.* at 7-8. She developed scarring, abdominal pain, and emotional injuries. *Id.*

The devices' packet inserts warned of the risk of erosion (Doc. 32-2 at Ex. 14). Dr. Schultheis was aware that risks associated with the devices included erosion, pain, and scarring at the time of Donaldson's surgery (Doc. 32-2, pp. 69-70). According to Dr. Schultheis, he would not have done anything differently with respect to his treatment of Donaldson and stands by his decision to recommend the devices. *Id*. at pp. 82-83. Dr. Schultheis continues to believe that the devices are safe and effective. *Id.*

Defendants' urologist expert, Dr. Douglas Grier, opined that mesh erosion is a known risk of the implant of a polypropylene pelvic mesh device and can happen for reasons other than a defect in the device. In his opinion, none of Donaldson's symptoms are attributable to any alleged defects in the devices.

In response to Defendants' motion for summary judgment, Plaintiffs filed the Declaration of Dr. P.D.L. Nayak, one of Donaldson's treating physicians, dated May 18, 2020 (Doc. 40-1). Dr. Nayak stated in pertinent part:

> 6. That all opinions expressed herein are true within a reasonable degree of medical certainty.
>
> 7. That the aforesaid mesh products implanted into my patient, Dianne M. Donaldson, during 2010 were defectively designed and unreasonably dangerous for the reason that they failed to perform as expected in light of their nature and intended function in that said products eroded into internal tissues of Dianne M. Donaldson, including but not limited to the vagina and bladder, resulted in development of bladder stones, and caused pelvic pain and suffering which the patient continues to experience. The failure of these

> products made necessary several surgical procedures for removal of mesh and bladder stones.
>
> 8. That, based upon my personal care and treatment of the patient, and upon the records of other physicians, many of which are attached hereto, there was no abnormal use of the products and there are no reasonable secondary cause [sic] for the failure of the products or the injuries sustained by the patient as aforesaid.

Id.

Defendants deposed Dr. Nayak on November 25, 2020 during which Dr. Nayak testified as follows: The Declaration did not reflect his opinions and that he was not offering any opinions related to Donaldson's TVT-Secur device (Doc. 56-4, pp. 64-65); the Prosima device effectively repaired Donaldson's prolapse (Doc. 56-4, p. 66); he did not evaluate whether there was an abnormal use of the device (*Id*. at pp. 77-78); and the Prosima device *was possibly defective* because Donaldson had mesh erosion. The following exchange took place with respect to whether Dr. Nayak was offering and opinion within a reasonable degree of medical certainty that the Prosima device was defective:

> Q. Okay. So basically, your opinion is that because Mrs. Donaldson had a Prosima implanted and then she had a mesh -- the mesh eroded, therefore, the Prosima must have been defective; is that accurate?
>
> A. Possibly defective.
>
> Q. Possibly?
>
> A. Yeah.
>
> Q. So you're not giving an opinion to a reasonable degree of medical certainty that the Prosima® was defective, correct?
>
> A. It possibly caused the mesh to be eroded into the bladder and caused stones. That's my opinion.
>
> Q. Okay. So your opinion is that the Prosima possibly caused the mesh to erode into the bladder, correct?
>
> A. Yes.

Q. And you're not giving an opinion that the Prosima was actually defective, correct?

A. Yes.

Q. Is that correct?

A. Yeah.

Q. Okay. So essentially, your opinion is that the Prosima possibly caused the mesh to erode into the bladder, but you're not saying that that had anything to do with a defective design of the Prosima, correct?

A. I don't know how the Prosima is designed, so I cannot comment on the design of the thing. But since it happened after that, I just thought it was related to the Prosima implantation. I don't know about the design of the Prosima.

Q. Okay. And when you say you don't know the design of the Prosima, is it accurate to say that you won't be giving any opinion about the design of the Prosima and whether or not it was defective, correct?

A. Yeah.

* * *

Q. So what I'm focused on is the word "possibly" that you're using. And that's different than saying -- saying that it's -- possible is different than saying that you have a reasonable degree of certainty that it actually was the cause, right?

A. Yes.

Q. And you're not giving an opinion to a reasonable degree of medical certainty here, correct?

A. Yes.

Id. at pp. 68-71.

Dr. Nayak further testified that the mesh erosion could have resulted from secondary causes such as vaginal atrophy, but he did not consider whether there were reasonable secondary causes of Donaldson's injuries. *Id.* His sole opinion is that mesh itself can cause complications, erosion into the bladder or the vagina, no matter who makes it. *Id*. at pp. 75-76.

Discussion

Motion to Strike (Doc. 57)

Defendants move to strike Dr. Nayak's Declaration, asserting that the Declaration (1) inaccurately purports to render opinions about the TVT-Secur mesh; (2) inaccurately states that Dr. Nayak believes within a reasonable degree of medical certainty that the Prosima device was defectively designed and caused Donaldson's erosion; (3) inaccurately states that Dr. Nayak determined that there was no abnormal use of the Prosima; and (4) inaccurately states that there are no other explanations for Donaldson's injuries. Plaintiffs concede that the portions of Dr. Nayak's Declaration which conflict with his deposition testimony should be stricken. They maintain, however, that the remainder of the Declaration – paragraphs 1 to 4 and portions of paragraphs 7 to 8 – should not be stricken.

A party may not survive a motion for summary judgment by manufacturing a factual dispute through the submission of an affidavit or declaration contradicting deposition testimony. *Amadio v. Ford Motor Co.,* 238 F.3d 919, 926 (7th Cir. 2001); *see also Darnell v. Target,* 16 F.3d 174, 177 (7th Cir. 1994) (noting that an affidavit which is contradicted by the affiant's deposition testimony is "without factual support in the record ... and cannot defeat a motion for summary judgment"). In the event of contradiction, the affidavit or declaration must be disregarded in favor of deposition testimony "unless it is demonstrable that the statement in the deposition was mistaken perhaps because the question was phrased in a confusing manner or because a lapse of memory is in the circumstances a plausible explanation for the discrepancy." *Piscione v. Ernst & Young, L.L.P.,* 171 F.3d 527, 532–33 (7th Cir. 1999) (quoting *Russell v. Acme–Evans Co.,* 51 F.3d 64, 67–68 (7th Cir. 1995)).

Here, Dr. Nayak's opinions relevant to resolving summary judgment are contained in paragraphs 6 to 8 of his Declaration. Significantly, contrary to his statement in paragraph 6, Dr. Nayak testified that his opinions regarding the devices are not stated to a reasonable degree of medical certainty. Dr. Nayak also testified that he was not giving any opinions regarding the TVT-Secur. His testimony also contradicts his statements in paragraphs 7 and 8 of the Declaration. Specifically, he testified: (1) that he was not giving an opinion that the Prosima was actually defective; (2) that he does not know how the device is designed and is not opining that the design was defective; (3) that he did not evaluate whether there was an abnormal use of the Prosima device; (4) that there are other possible explanations for her erosion; and (5) that he did not consider any other potential secondary causes for the failure of the products or the injuries that Donaldson had. Based on Dr. Nayak's unequivocal testimony which materially contradicts his Declaration, Defendants' Motion to Strike is **GRANTED**; the Court will not consider Dr. Nayak's Declaration in ruling on Defendants' motion for summary judgment.

Motion for Summary Judgment (Docs. 31 and 56)

Summary judgment is proper only if the moving party can demonstrate that there is no genuine issue as to any material fact. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett,* 477 U.S. 317, 322 (1986). The moving party is entitled to summary judgment where the non-moving party "has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Celotex,* 477 U.S. at 323. If the evidence is merely colorable, or is not sufficiently probative, summary judgment may be granted. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 249–50 (1986). Any doubt as to the existence of a genuine issue of material fact must be resolved against the moving party. *Lawrence v. Kenosha County,* 391 F.3d 837, 841 (7th Cir. 2004). Nevertheless, the "favor toward the nonmoving party does not extend to drawing

inferences that are supported by only speculation or conjecture." *Monroe v. Ind. Dep't of Transp.*, 871 F.3d 495, 503 (7th Cir. 2017) (internal quotations and citations omitted).

Conceded Claims

Plaintiffs concede summary judgment as to Counts I through III and Counts VI through XV. Accordingly, the Court grants Defendants' motion as to those counts. As to Plaintiffs' claims for punitive damages (Count XVII) and discovery rule and tolling (Count XVIII), these are not separate causes of action or standalone claims. Rather, punitive damages are a remedy and the discovery rule and tolling are defenses to a statute of limitations argument. Accordingly, Counts XVII and XVIII are subject to summary dismissal.

Strict Liability

Plaintiffs' remaining claims (Counts IV and V) assert strict liability predicated on an alleged design defect with the devices. To recover in a strict product liability action, a plaintiff must plead and prove that the injury complained of resulted from a condition of the product, that the condition was unreasonably dangerous, and that it existed at the time the product left the manufacturer's control. *Mikolajczyk v. Ford Motor Co.,* 901 N.E.2d 329, 335 (2008). A product may be determined to be unreasonably dangerous based on proof of any one of three conditions: (1) a physical defect in the product itself (manufacturing defect); (2) a defect in the product's design (design defect); or (3) a failure of the manufacturer to warn of the danger or to instruct on the proper use of the product (failure to warn). *Mikolajczyk,* 901 N.E.2d at 335. Because Plaintiffs have conceded summary judgment as to their manufacturing defect and failure to warn claims, only their design defect claim remains for the Court's consideration.

A design defect claim requires Plaintiffs to establish: (1) a condition of the product as a result of design, (2) that made the product unreasonably dangerous, (3) and that existed at the time

the product left the defendant's control, and (4) an injury to the plaintiff, (5) that was proximately caused by the condition. *Clark v. River Metals Recycling, LLC*, 929 F.3d 434, 439 (7th Cir. 2019) (citing *Mikolajczyk,* 901 N.E.2d at 345). Here, Defendants argue that Plaintiffs cannot prove a design defect claim in the absence of expert proof.

In most cases, products liability actions alleging design defects require expert testimony to prove that a product defect was unreasonably dangerous and proximately caused the plaintiff's injuries. *See Baltus v. Weaver Division of Kidde & Co.,* 557 N.E.2d 580 (1990). More specifically, when specialized knowledge or expertise of a product defect is "outside the layman's knowledge," an expert is needed to assist the jury's understanding of whether a product is unreasonably dangerous. *Id.*, 557 N.E.2d at 588–89. A jury cannot be allowed in the absence of expert testimony to "speculate that [the product] was in fact an unreasonably dangerous" one. *Id; see also Show v. Ford Motor Co.*, 659 F.3d 584, 585 (7th Cir. 2011) ("Several intermediate appellate decisions in Illinois say that expert testimony is vital in design-defect suits when aspects of a product's design or operation are outside the scope of lay knowledge.").

Plaintiffs argue that expert proof is unnecessary to establish their design defect claim. Relying on *Tweedy v. Wright Ford Sales*, 357 N.E.2d 449 (1976), they contend they may prove their claims with circumstantial evidence in the absence of expert proof. The *Tweedy* doctrine is variant of *res ipsa loquitur* and allows a plaintiff to present a product liability case in the absence of expert testimony. Under the doctrine, a plaintiff may rely on circumstantial evidence establishing: (1) there was no abnormal use of the product, (2) there are no reasonable secondary causes of the malfunction, and (3) the product failed to perform in the manner reasonably to be expected in light of its nature and intended function. *Tweedy*, 357 N.E.2d at 452. The doctrine applies only if the jury can reasonably infer that the plaintiff's injury resulted from a condition of

the product, the condition was unreasonably dangerous, and the condition existed when it left the defendant's control. *Show v. Ford Motor Co.*, 697 F. Supp. 2d 975, 984 (N.D. Ill. 2010), *aff'd*, 659 F.3d 584 (7th Cir. 2011); Illinois Pattern Jury Instructions, Civil, No. 400.01.01 (2009). The circumstantial evidence must justify an inference of probability, as distinguished from mere possibility – liability cannot be predicated on mere speculation, guess, or conjecture. *Id.; see also Varady v. Guardian Co.,* 506 N.E.2d 708, 711 (1987).

This Court does not believe that the *Tweedy* doctrine can appropriately be applied in complex medical device cases. These devices are not simple products that lay jurors commonly use or see and their functions are, therefore, beyond a jury's common knowledge, experience or understanding. That is why expert testimony is needed to assist the jury's understanding of whether a product is unreasonably dangerous. Without the aid of expert testimony, the jury can only speculate as to what inferences to draw. *See Fulton v. Theradyne Corp.*, 2007 WL 772953, at *4 (N.D. Ill. Mar. 12, 2007) (granting summary judgment on design defect claim where the plaintiff failed to present admissible expert evidence regarding the design of a medical device). Thus, the question of whether the devices in question were defective and caused Donaldson's alleged injuries is a complex issue that requires expert interpretation and proof.

Moreover, even under *Tweedy*, Plaintiffs are required to make a *prima facie* case that the devices were defective and that the defect existed when it left the manufacturer's control by proof that in the absence of abnormal use or reasonable secondary causes, the product failed to perform in the manner reasonably expected in light of its nature and intended function. *Tweedy*, 357 N.E.2d at 452. Here, Plaintiffs have not negated the possibility of reasonable secondary causes or that the product failed to perform as reasonably expected. While Plaintiffs maintain that Dr. Nayak's testimony provides the circumstantial evidence needed to trigger the *Tweedy* doctrine, Dr. Nayak

specifically testified that he did not consider and does not know whether there was abnormal use of the devices. And, he never considered whether there were reasonable secondary causes for the mesh erosion and Donaldson's injuries, although he acknowledges that vaginal atrophy or surgical technique could have been a reasonable secondary cause for her injuries. Dr. Nayak also opines that the Prosima device effectively repaired Donaldson's prolapse. Stripped down to its essence, his opinion regarding design defect is that one of the devices was "possibly" defective – an opinion that he could not provide to a reasonable degree of medical certainty. That opinion is based on his assumption that because the mesh eroded, it was possibly defective. But the fact that an injury occurred does not in and of itself prove that a product is defective.

By contrast, Defendants' expert urologist and pelvic surgeon, Dr. Grier, opines, to a reasonable degree of medical certainty, that "the occurrence of a bladder or vaginal erosion is not indicative of a product defect" and that there are alternative explanations for the erosion and Donaldson's injuries that are unrelated to her mesh devices, including her prior surgical procedures, her atrophic vaginitis, and surgical technique (Doc. 56-3, pp. 8–11). He also opines that the erosion of the Prosima device into Donaldson's bladder was, more likely than not, due to surgical technique – likely implanting the mesh in too deep a plane. *Id.* at 11.

Plaintiffs have produced no evidence to refute Dr. Grier nor is there circumstantial evidence sufficient to establish a *prima facie* case under *Tweedy*. Accordingly, summary judgment will be granted with respect to Plaintiffs' product defect claims.

Loss of Consortium

Defendants are also entitled to judgment as a matter of law on Dale Donaldson's consortium claim. The claim is derivative and is viable only to the extent his wife's claims survive. *Johnson v. May,* 585 N.E.2d 224, 232 (Ill. App. 1992) ("To recover on a loss of consortium claim,

the deprived spouse must prove liability on the part of the defendant, marriage to the injured spouse, and damages").

Conclusion

For the foregoing reasons, Defendants' Motion for Summary Judgment (Doc. 31), Supplemental Motion for Summary Judgment (Doc. 56), and Motion to Strike (Doc. 57) are **GRANTED**. The Clerk of Court is **DIRECTED** to enter judgment accordingly and to close this case.

IT IS SO ORDERED.

DATED: May 4, 2021

STACI M. YANDLE
United States District Judge